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Computerised cognitive behaviour therapy for dementia carers

Submission date
06/02/2013

Recruitment status
No longer recruiting

Registration date
28/02/2013

Overall study status
Completed

Last Edited
11/10/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a devastating condition, which is emotionally and physically draining for the person with dementia and their carer. Carers of people with dementia are integral to providing a better quality of life for the person who they care for and substantially reducing the cost of dementia to society. Yet the burden and isolation experienced by carers leads to high incidence of stress and mental health problems, with over 50% of carers requiring medication to treat depression. Carers require regular support to maintain their own health and wellbeing and to support them in providing quality care for the person with dementia. Although some support services are available, carers are often unable to access it due to the time constraints involved in full time care and the lack of flexibility in location and format of services. Cognitive Behavioural Therapy (CBT) is an effective psychological intervention approach, which helps people to improve their coping strategies by working through their thoughts, feelings and behaviour. CBT has been shown to be an effective treatment for important health problems including depression, anxiety and pain. More recently, CBT has been shown to be effective for carers of people with dementia when delivered in person by a therapist. CBT has also been shown to be effective for depression, anxiety and pain when delivered online with telephone support. We want to find out whether online CBT with or without telephone support is effective in improving mood, reducing stress and improving coping strategies in carers of people with dementia. To do this we are going to compare the benefits of online CBT with regular telephone support, online CBT without telephone support and information about dementia without CBT in a clinical trial of 750 carers of people with dementia over 6 months.

Who can participate?
Anyone over the age of 18 caring for individuals with dementia living in the UK will be invited to participate. They will complete evidence-based rating scales to assess their levels of anxiety or depression. Participants depression of mild/moderate severity (score of 5-15 on PHQ9 rating scale) or anxiety of mild/moderate severity (score of 5-15 on GAD7 rating scale) will be eligible. We will exclude participants who score over 15 on PHQ9 or GAD7 or have active suicidal ideation (scores 2 or 3 on Q9 of PHQ9), are currently receiving a psychological therapy, treatment for alcohol abuse or abuse of illicit drugs, or treatment for a psychotic disorder. We will also exclude people with severe auditory or visual impairment that precludes use of the package, or who are physically unable to use a computer.

What does the study involve?
People wishing to participate and meeting the inclusion criteria will be randomly allocated to one of the three treatment arms. Ineligible participants will be able to access the online information package should they wish to, but no data will be collected. All participants will be asked to agree to an online consent form before undertaking further assessment. After completing consent, participants will be asked to provide basic demographic data including their contact number, age, gender and ethnicity, before completing screening. Participants will also be asked to provide their GP details. Existing CBT programmes typically last approximately eight hours. This programme will be a similar length but will be split into 20 sessions of around 20 minutes with the intention of delivering a programme which may be more user-friendly for carers with busy caring commitments. The control intervention in arm 3 will be delivered in the same format.
Every CBT session will also include:
1. Project overview (other than session 1)
2. Homework setting
3. Measures
4. Progress reports
5. Session summary and printout.
The telephone support provided in arm 2 will consist of six to ten telephone support calls with a practitioner trained in cCBT support based within IAPT services in Oxford Health. It will be an important consideration to ensure that any individuals with significant suicidal ideation receive appropriate help. Therefore, individuals who score 2 or more on the suicidal ideation question (Q9) of the Patient Health Questionnaire 9 (PHQ9) rating scale will not be eligible to participate and will be signposted to appropriate help and treatment. People who develop significant suicidal ideation during the study or score >19 on PHQ9 will be contacted by a telephone support worker to discuss their situation. The telephone support worker will also contact the participants' GP to inform them of the increase in levels of distress. The study will only be able to show whether the treatments are beneficial if the majority of participants continue to engage with the intervention. Substantial development time has therefore been put into developing a Cognitive Behavioural Therapy (CBT) package which is visually attractive and engaging, including the use of multimedia functionality, to maximize retention in the study. As part of the therapy participants will be given feedback about their progress in the study. The supported group will be given additional feedback based on routine IAPT monitoring. The control arm participants will be given information about dementia in a modular package.

What are the possible benefits and risks of participating?
Evidence has shown that online interventions are effective in changing behaviour and conferring clinically significant benefit in randomised controlled trials. Participants taking part in this study will therefore benefit from a psychological intervention that could reduce their levels of anxiety and depression. They will also have the benefit of attending a therapy remotely, as many do not have the time or location flexibility to attend face-to-face support services due to their demanding caring role. The risk associated with participating in this trial is related to the severe levels of depression or anxiety that carers may still experience during the study. Participants in such conditions who are not allocated to the telephone supported arm can access our online guidance for alternative forms of support and will be contacted by a research telephone support worker to discuss their situation should their PHQ9 scores indicate they are experiencing increased levels of distress. Their GP will also be informed of their increased scores. Those participants whose score in the depression scale identifies suicidality risk upon registering will be prevented from taking part in the trial.

Where is the study run from?
Oxford Health NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
The study will run from May 2015. All participants will be followed for 26 weeks, and there will be a recruitment window of 6 months. We anticipate the study to finish in April 2017.

Who is funding the study?
The Commissioned Research programme of the Alzheimer's Society.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Can online Cognitive Behavioural Therapy lead to sustained improvement in mood and other key outcomes in people caring for individuals with dementia? A randomized controlled trial

Study objectives
1. Does online CBT with telephone support give significantly greater improvement in mood (improvement in the GHQ-12 scale), than providing online information about dementia alone over 26 weeks in carers with significant symptoms of depression or anxiety at baseline.
2. Does online CBT without telephone support give significantly greater improvement in mood (improvement in GHQ-12 rating scale), than providing online information about dementia alone over 26 weeks in carers with significant symptoms of depression or anxiety at baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central REC B, 03/06/2013, 13/SC/0117

Primary study design
Interventional

Study design
26-week three-arm randomized placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety and depression

Interventions
Arm 1: 20 session cCBT package
Arm 2: 20 session cCBT package with telephone support
Arm 3: 20 session online carer information package (control)

Arm 1: Online cCBT, accessed through the internet (250 participants)

An online CBT package will include materials to support participants, including learning in dementia and CBT skills to reduce carer burden, stress, distress and depression. The intervention will be structured as an eight or twelve session online resource based on the Oxford Health NHS Foundation Trust CBT protocol for clinically depressed carers. The key elements will be:
1. Education on understanding dementia, people with dementia's reactions to stress, carers reactions to stress
2. Stress management using CBT framework
3. Relaxation and problem solving skills for making time for relaxation
4. Identifying unhelpful thoughts and reactions and learning new skills
5. Identifying lifestyle and support factors
6. Developing coping strategies

All of the elements will be based on a CBT framework to identify and understand difficulties, using interactive processes which have been successfully used in other online packages such as 'Beating the blues', 'Pathways through pain' and 'Breaking free'.

Every session will also include:
1. Project overview (other than session 1)
2. Homework setting
3. Measures
4. Progress reports
5. Session summary and printout.

Arm 2: Online cCBT with telephone support (250 participants)
This will deliver all of the elements outlined in Arm 1 with additional telephone support. This will consist of six - ten telephone support calls with a practitioner trained in cCBT support based

within IAPT services in Oxford Health NHS Foundation Trust. The sessions will utilise an operationalized cCBT support model including monitoring and feedback adapted from the Oxford CBT protocol.

Arm 3: Control group (250 participants)
Alzheimer's Society will provide a full, quality, approved information and modular information package about dementia for carers, designed to provide an equivalent amount of computer time to the cCBT packages. This will include factsheets from the Society.

Consent and Screening
All participants will be asked to agree to an online consent form before undertaking further assessment. After completing consent, participants will be asked to complete screening questionnaires. This will include a short self report screening questionnaire on the inclusion criteria to determine eligibility, including the PHQ9, the GAD7 and whether they are receiving any other current psychological therapies. They will also be asked about any current treatment for abuse of alcohol or illicit drugs, a current psychotic disorder or ongoing treatment with a psychological intervention. Participants will then be asked to provide basic demographic data including their age, gender, ethnicity, relationship to person with dementia (partner, child, spouse, etc), their level of dementia (mild, moderate, severe), length of time as a carer, place of residence and educational attainment.

Adverse Events
An Adverse Event (AE) is defined as any untoward medical occurrence in a patient or clinical study subject.

A Serious Adverse Event (SAE) is defined as any untoward and unexpected medical occurrence or effect that:
1. Results in death
2. Is life-threatening - refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
3. Requires in-patient hospitalisation, or prolongation of existing inpatients' hospitalisation
4. Results in persistent or significant disability or incapacity

Each participant will be given clear guidance on how to access an on-line section for concerns, complaints or adverse events.

AE and SAE will be directed to the Chief Investigator in the first instance and all SAEs will be sent to the chair of the DMEC within 24 hours of receipt.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 11/05/2015:
General Health Questionnaire (GHQ12) at 26 weeks

Previous primary outcome measures:
General Health Questionnaire (GHQ12) which will be rated at baseline, week 12 and 26

Key secondary outcome(s)

Additional key secondary outcome measures undertaken at baseline, weeks 12 and 26 will include:
1. The Hospital Anxiety and Depression Scale (HADS) to measure anxiety and depression
2. The Short Sense of Competency Questionnaire (SSCQ) to measure sense of mastery
3. The Short Form 6D (SF6D) as a short health-related quality of life measure
4. The Relative Stress Scale (RSS) as a measure of stress
5. The Carers of Older People in Europe (COPE) scale as a measure of social support
6. The short Client Services Receipt Inventory (CSRI) to enable health economic analysis

Added 11/05/2015:
An additional measure, the Credibility and Expectancy Questionnaire (CEQ), will be rated at baseline only to enhance our understanding of possible mediating factors for treatment efficacy and response.

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/05/2015:
1. Aged 18 or over.
2. Caring for someone with dementia
3. Depression of mild/moderate severity (Score of 5-15 on PHQ9 rating scale) OR anxiety of mild /moderate severity (Score of 5-15 on GAD7 rating scale)
4. Living in the UK
People wishing to participate and meeting the inclusion criteria will be randomized to the three treatment arms. Ineligible participants will be able to access the online information package should they wish to, but no data will be collected.

Previous inclusion criteria:
1. Caring for someone with dementia
2. Depression of at least mild severity (Score of 5 of above on PHQ9 rating scale)
OR Anxiety of at least mild severity (Score of 5 or more on GAD7 rating scale)
3. Living in the UK

People wishing to participate and meeting the inclusion criteria will be randomized to the three treatment arms. Other participants will be able to receive the online cCBT without telephone support or information.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Active suicidal ideation (score of 2 or more on Q9 of PHQ9 rating scale)
2. Currently receiving a psychological therapy
3. Currently receiving treatment for alcohol abuse or abuse of illicit drugs
4. Currently receiving treatment for a psychotic disorder
5. Severe auditory and / or visual impairment that precludes use of the package
6. Physically unable to use a computer or are not sufficiently motivated to commit to the therapy
7. Under 18 years of age

Date of first enrolment
30/05/2015

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Health NHS Foundation Trust
Oxford
United Kingdom
OX3 7JU

Sponsor information

Organisation
Oxford Health NHS Foundation Trust (UK)

ROR
https://ror.org/04c8bjx39

Funder(s)

Funder type
Charity

Funder Name
Nominet Trust (UK)

Funder Name
Stavros Niarchos Foundation

Funder Name
Improving Access to Psychological Therapies (IAPT) National Programme (UK) - Department of Health

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes